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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,889

08/18/2005

Rudy Hengelmolen

1768-135

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7590

09/19/2008

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WASHINGTON, DC 20005

EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

3734

NOTIFICATION DATE

DELIVERY MODE

09/19/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/522,889	Applicant(s) HENGELMOLEN, RUDY	
	Examiner Eric Blatt	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 9, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2-1-2005; 6-16-2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 9 and 11-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 16, 2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the first and second ends of the lumen are open "such that fluid flow occurs through said lumen." It is unclear if the fluid is being positively recited. Examiner suggests amending this language to recite, "such that fluid flow can occur through said lumen."

Claim 5 recites, "a plurality of longitudinally elongate strips fo interconnected hexagons oriented along said longitudinal axis of said tubular liner." It appears "fo" should instead read "of." Additionally, it is not clear whether claim 5 recites that the elongate strips are oriented along the longitudinal axis or, alternatively, that the interconnected hexagons are oriented along the longitudinal axis.

Claim 10 provides for the use of a tubular liner, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

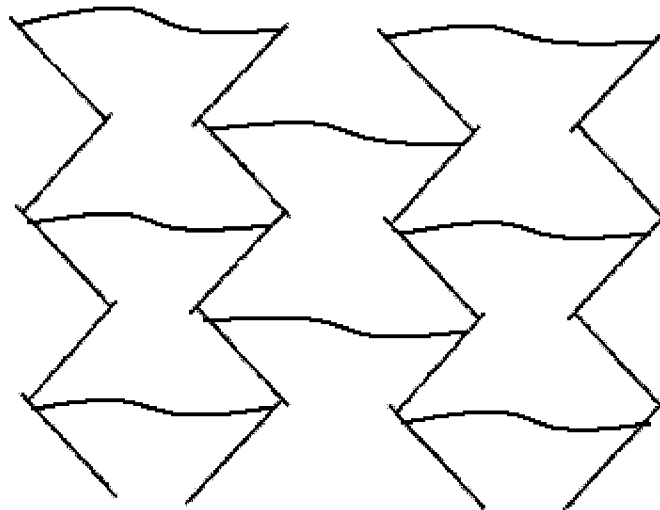
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgermeister (US 2002/0123798) in view of Sridharan et al. (US 2003/0124279).

Burgermeister discloses a tubular liner (Figures 8-10) for insertion into a duct comprising first and second ends and a lumen such that fluid flow occurs through said lumen from the first end to the second end. Regarding the claimed strut patterning, Burgermeister discloses that the tubular liner has radial portions 410 joined together by connecting members 410 (Figure 8A). Although radial portions 410 comprise curved struts, it can be seen that these radial portions essentially comprise zig-zagging struts. Burgermeister discloses that by affixing the connecting members near the inner vertexes of adjacent radial zig-zagging portions, the stent may be caused to increase in length as it expands radially. (Figures 9 and 10) Extrapolating the arrangement of the connecting member shown at the top of Figure 10 across an entire stent, the strut pattern would appear as shown in the sketch below.



Burgermeister does not explicitly disclose that the connecting members may be affixed exactly at the inner vertexes, but rather teaches that the nearer the connecting members are attached to the inner vertexes, the more the stent will increase in length as

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it radially expands. It would have been obvious to one of ordinary skill in the art at the time of the invention to affix the connecting members to the inner vertices in order to maximize the lengthening property as taught by Bergermeister. Thus, Bergermeister teaches a tubular liner comprising a plurality of adjacent radial loops wherein each loop comprises a plurality of interconnected hexagons as claimed in claims 2-4. The connecting members comprise first and second hexagon sides parallel to the longitudinal axis.

Regarding claims 5-8, the bands interconnected hexagons of Bergermeister are oriented radially. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Bergermeister by orienting the bands of interconnected hexagons longitudinally to form elongated strips since such a modification would have merely required a rearrangement of the existing parts of the device and would not have produced unexpected results. Additionally, such an arrangement would also have been useful in reducing foreshortening of the stent during radial expansion. Reoriented as such, the connecting members comprise first and second hexagon sides perpendicular to the longitudinal axis.

Regarding the recitation that the tubular liner comprises a synclastic lumen, Bergermeister discloses that the stent may be expanded by means of a balloon. It would have been obvious to use a balloon that expands first in a middle portion since such balloons were notoriously old and well known in the art and their use would not have produced unexpected results. During expansion of the tubular liner with such a balloon, the lumen of said liner would be synclastic.

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Thus, Bergermeister discloses or teaches all elements of claims 1-8 except that the tubular liner is formed from an auxetic material. Sridharan teaches that it was known to form medical devices from auxetic materials. (Paragraphs 5, 13) It would have been obvious to one of ordinary skill in the art to form the tubular liner from an auxetic material since it has been held that it is within the knowledge of one of ordinary skill in the art to select a known material for forming a device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735.

The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Eric Blatt
571-272-9735